THE HONORABLE RONALD B. LEIGHTON

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

CURTIS PEDERSON, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	Case No. 3:20-CV-05216-RBL JOINT STATUS REPORT AND DISCOVERY PLAN

Pursuant to Federal Rule of Civil Procedure 26(f), LCR 26(f), and the Court's order of March 31, 2020 (Dkt. No. 9), the parties now jointly enter the following Joint Status Report and Discovery Plan. The parties met and conferred on June 15, 2020, and have cooperated in the preparation of this Report.

I. JOINT STATUS REPORT

1. Statement of the Nature and Complexity of the Case.

Plaintiff:

This is an action brought by Curtis Pederson (hereinafter, "Plaintiff"), against Defendant Novartis Pharmaceuticals Corporation (hereinafter, "NPC") to recover for injuries resulting from NPC's failure to warn of significant risks associated with Tasigna – a Novartis-manufactured prescription medication for treatment of chronic myeloid leukemia ("CML"). Specifically, NPC failed to warn that Tasigna can cause severe, rapidly evolving, irreversible

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vascular disease often involving more than one site. NPC failed to warn that the nature of vascular disease caused by Tasigna could be so severe it could require repeat revascularization procedures, that often fail, and ultimately result in serious complications such as limb necrosis and amputations. Despite warning doctors and patients in Canada of the risks of atherosclerotic-related conditions, NPC concealed, and continues to conceal, its knowledge of Tasigna's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community in the United States.

While NPC updated the label for Tasigna in January 2014, approximately five months *after* Plaintiff was first prescribed Tasigna, to include a warning entitled "Cardiac and Vascular events", this warning was and remains wholly inadequate. Indeed, unlike the Canadian product labeling, the label in the United States, to this day, does not contain warnings regarding any of the risks described above. Further, in contrast to the Canadian warning, this warning was not added as a "black box warning", the most prominent warning placed on a label in order to properly and adequately advise physicians of significant risks.

After beginning treatment with Tasigna and as a direct and proximate result of NPC's actions and inactions, Plaintiff suffered serious atherosclerotic-related injuries. Specifically, as a result of his use of Tasigna, Plaintiff suffered rapidly progressing system-wide atherosclerotic disease including, severe coronary artery disease, multiple cerebellar strokes, cerebrovascular disease, severe stenosis of his carotid artery, and rapidly progressing peripheral vascular disease. To date, these conditions have required several procedures, including, a popliteal angioplasty, femoral popliteal bypass surgery, third-order catheterization, and multiple procedures to treat the wounds associated with his lower extremity surgeries, which left him with severe open wounds. Plaintiff remains at significant risk of further complications as a result of these conditions.

As a result of his injuries, Plaintiff seeks damages including but not limited to the following:

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a. General damages;

b. Medical and incidental expenses, including Plaintiff's need for life long care;

c. Losses related to Plaintiff's inability to pursue his usual occupation and activities;

d. Pain and suffering and emotional distress according to proof;

e. Punitive and exemplary damages;

f. Plaintiff's reasonable attorneys' fees and costs;

g. Prejudgment interest; and

h. Any other relief this Court deems appropriate.

Defendant:

NPC generally denies all allegations in the Complaint and Jury Demand ('the Complaint") of plaintiff. NPC's product Tasigna® is a cancer medication that is FDA-approved to treat patients with Philadelphia chromosome positive chronic myeloid leukemia ("CML"). CML is a blood cancer that causes the body to overproduce white blood cells. Unchecked, CML is a fatal disease. As of 2016, CML had a 69.2% five-year survival rate, up from 47.9% in 2000. The significant increase in survival between 2000 and 2016 paralleled the increase in the availability of tyrosine kinase inhibitor ("TKI") medicines, including NPC's Tasigna®. Tasigna® has been shown to be superior to its predecessor TKI treatment, Gleevec®, in treating CML. NPC denies that that there are any defects associated with Tasigna®.

Plaintiff will be unable to meet his burden to prove that Tasigna® can cause cardiovascular disease and that Tasigna® caused his alleged injuries. Plaintiff also will be unable to prove that the FDA-approved labeling for Tasigna® was inadequate. On January 22, 2014, Novartis updated the Tasigna® prescribing information in the United States to include a Warning & Precaution Section dedicated to Cardiac and Vascular Events. The Highlights of Prescribing Information on the first page stated:

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> Cardiac and Vascular Events: Cardiovascular events including ischemic heart disease, peripheral arterial occlusive disease and ischemic cerebrovascular events have been reported in patients with newly diagnosed Ph+CML receiving nilotinib. Cardiovascular status should be evaluated and cardiovascular risk factors monitored and managed during Tasigna® therapy.

Plaintiff's complaint states that plaintiff continued Tasigna® therapy for two years after this label change.

This case implicates an array of scientific, medical, and regulatory issues that will be the subject of wide-ranging expert reports and testimony. NPC anticipates that the parties will designate a dozen, or perhaps more expert witnesses (six per party, or more), which does not include the numerous treating physicians who will need to be deposed. NPC expects that it will seek evidentiary hearings on its *Daubert* motions that will challenge the admissibility of plaintiff's experts.

NPC will request that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

2. Proposed Deadline for the Joinder of Additional Parties

Motions to add parties to be electronically filed by October 25, 2020.

Plaintiff requests that the Court require motions to amend pleadings to be electronically filed by September 25, 2021. NPC requests that the Court require motions to amend pleadings to be electronically filed by May 1, 2021.

3. Assignment to a U.S. Magistrate Judge

The parties do not consent to assignment of this case to a U.S. Magistrate. Per LCR 73, the Parties reserve the right to a later request for assignment of the case to a U.S. Magistrate Judge.

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II. DISCOVERY PLAN

(A) Initial Disclosures

The parties exchanged disclosures by June 22, 2020, which is the date set by the Court.

(B) Subjects, Timing, and Potential Phasing of Discovery

(1) Discovery is needed on the following subjects:

Plaintiff:

Prior to the commencement of this action, claims alleging atherosclerotic-related injuries caused by Tasigna were filed against NPC in the Eastern District of California (Kristi Lauris v. Novartis AG et al., 1:16-cv-00393-LJO-SAB) and the Southern District of Florida (Dennis McWilliams v. Novartis AG et al., 2:17-cv-14302-RLR). Counsel for Plaintiff here did not appear in these actions. Both of these cases were resolved shortly before scheduled trial dates and after the completion of fact and expert discovery and subsequent denial of NPC's Summary Judgement Motion.

The parties are meeting and conferring as to the whether the discovery conducted in those cases may be applicable to the matter at bar. Plaintiff's counsel here, does not have knowledge of the extent of this prior discovery and therefore reserves all rights to conduct discovery on all matters relevant to the claims and defenses herein. In order to facilitate this process, Plaintiff requested an initial, informal exchange of certain information. Defendant has provided some preliminary information and the parties are continuing to meet and confer to determine the scope of discovery that was completed in the prior actions and the additional discovery needed here. There is undoubtedly additional discovery that will be required to address the needs of this case.

For example, Plaintiff is aware that the timeframe covered by the discovery conducted in those two cases ended in approximately 2014. Plaintiff will seek additional discovery up to the present. There are also likely to be additional areas of discovery relevant to the particular claims and defenses which are unique to this particular case which the parties intend to discuss.

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At this time Plaintiff anticipates he will request discovery into NPC's conduct surrounding the following areas as they relate to Tasigna® along with any additional areas of discovery that may be revealed as the case progresses:

a. Licensing;
b. Research & Development;
c. Patents;
d. Preclinical Development;
e. Clinical Development;
f. Medical Affairs;
g. Medical Coding;
h. Pharmacovigilance/Drug Safety;
i. Health Insurance Reimbursement;
j. Life Cycle Management;
k. Marketing;
l. Labeling;
m. Market Research;
n. Sales and Sales Training;
o. Key Opinion Leaders and/or Speakers' Bureaus;
p. Budgeting; and
q. Regulatory or compliance functions, including those related to the FDA and other foreign regulatory bodies

Finally, the Court should be aware there are 31 cases involving similar claims currently pending in several Federal Districts across the United States, as well as in New Jersey State Court. The parties are discussing coordination of discovery in these actions.

Defendant:

NPC will, among other things, seek discovery on

- Plaintiff's medical condition, pre-existing medical conditions, family medical history, and risk factors for cardiovascular events;
- Plaintiff's alleged injuries and damages, including in the form of tax, employment, and social media records;
- Plaintiff's and prescribing physicians' knowledge of CML, Tasigna®, cardiovascular events, and all information obtained regarding the same; and
- The opinions of plaintiff's designated expert witnesses.

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NPC disputes that discovery will be necessary for the full scope of the seventeen subject matters identified by plaintiffs. Discovery in this case includes the need to obtain copies of medical records from plaintiff's healthcare providers. NPC has been given some medical records by plaintiff's counsel voluntarily. NPC cannot tell at this stage whether those collections are complete, and there are additional providers whose records will be relevant and will need to be collected. NPC is entitled to use the discovery process to ensure access to complete medical files regarding the plaintiff. The records collection process takes time, and is iterative in nature. As each set of records is received, they must be reviewed, and follow-up undertaken, to ensure that the provider has produced a complete set of records. Also, review of collected records inevitably leads to the identification of additional healthcare providers or locations of treatment, and new requests must be made to collect those. Although the parties work diligently to collect records, often facilities take significant amounts of time to respond to requests.

(2) Timing of discovery.

i. Fed. R. Civ. P. 26 Initial Disclosures: June 22, 2020.

ii. Service of initial written discovery: on or before August 30, 2020, which shall be responded to by September 30, 2020.

iii. Maximum of 25 Interrogatories, including subparts, with initial interrogatories to be served on or before August 30, 2020, which shall be responded to by September 30, 2020.

iv. Maximum of 10 depositions of fact witnesses to be taken by each party.

The parties agree that any presumptive limit on the number of depositions applies only to fact witnesses, and that depositions of the parties' designated experts should not count toward the parties' limits. Further, as detailed above, the parties are actively meeting and conferring regarding the discovery conducted in the two prior litigations. The number of depositions Plaintiff requests in this case will likely depend on that prior discovery. However,

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at this time, Plaintiffs do not anticipate requesting more than fifteen (15) depositions of fact witnesses. NPC states that it does not believe that Plaintiff should require more the presumptive limit of 10 depositions, especially in light of the extensive deposition discovery that occurred in prior cases. After the parties have met and conferred regarding previous discovery and depositions and what additional discovery is needed, Plaintiff will confer with NPC in an attempt to reach an agreement as to the number of additional depositions required at this time. Plaintiff also anticipates that depositions of NPC's fact witnesses can be coordinated with those cases pending in other Federal Courts and the State of New Jersey, so as to avoid duplicative efforts. The parties reserve their right to seek additional fact depositions by agreement of the parties or by Court order.

v. Factual discovery to be completed by March 30, 2021 (Plaintiff) / April 30, 2021 (NPC).

vi. Plaintiff's expert reports due on April 21, 2021 (Plaintiff) / May 21, 2021 (NPC).

vii. Defendant's responsive expert reports due on May 18, 2021 (Plaintiff) / June 18, 2021 (NPC).

viii. Plaintiff's expert depositions to be completed by June 30, 2021 (Plaintiff) / July 30, 2021 (NPC).

ix. Defendant's expert depositions to be completed by July 27, 2021 (Plaintiff) / August 27, 2021 (NPC).

(3) Discovery should be conducted in phases.

The parties request that expert discovery take place following the completion of fact discovery. NPC further requests that the depositions of plaintiff's experts take place prior to the depositions of NPC's experts.

(C) Electronically Stored Information

The parties intend to submit a proposed ESI Protocol or, in the alternative, briefing of

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any issues that cannot be agreed upon by August 28, 2020. The Parties intend to comply with the letter and spirit of FRCP 34(b)(2)(E).

(D) Privilege Issues

The Parties anticipate that confidential, proprietary, and/or commercially sensitive information as well as information protected from disclosure under the Privacy Act, HIPAA, and/or any other applicable provision/privilege will be sought during the course of discovery. The Parties will work together to agree upon a Stipulated Protective Order, based upon the Western District of Washington's Model Protective Order, with modifications consistent with protective orders entered in prior Tasigna® cases, to govern the production and use of such documents.

(E) Proposed Limitations on Discovery

The parties are not asking the Court to limit discovery at this time.

(F) The Need for any Discovery Related Orders

Other than the agreed Rule 502(d) Order (section III.H below) and a Stipulated Protective Order that the parties will submit (section II.D above), the parties at this time do not seek the entry of additional discovery-related orders.

III. PARTIES' VIEWS, PROPOSALS, AGREEMENTS PER LOCAL RULE 26(F)(1)

(A) Prompt Case Resolution

The parties have discussed the possibility of resolution prior to filing of suit. The parties agree to engage in private mediation once the case has proceeded further, following the conclusion of discovery or after the resolution of dispositive motions.

(B) Alternative Dispute Resolution

The Parties agree that this case may be amenable to Alternative Dispute Resolution at an appropriate time pursuant to Local Civil Rule 39.1.

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(C) Related Cases

A different plaintiff filed a claim alleging injuries caused by Tasigna® against NPC in the Western District of Washington (*Bruce Becker v. Novartis Pharmaceuticals Corporation*, 3:20-CV-05221-BHS). There are currently 31 additional pending Tasigna® cases that have been filed in federal courts and in New Jersey state court.

(D) Discovery Management

The parties met and conferred on June 15, 2020 to discuss discovery management in this matter. The Parties agree to cooperate in efficient discovery.

(E) Anticipated Discovery Sought

The parties anticipate discovery to include, but not limited to, the following subjects:

- Fact discovery relating to plaintiff, including medical and employment history
- Corporate discovery, as described in section II (B) above;
- Independent medical examination;

Expert discovery, including on general and specific causation; and

- Depositions of fact and expert witnesses.

(F) Phasing Motions

Plaintiffs propose filing all motions to dismiss, motions for summary judgment and other dispositive motions, together with supporting papers no later than September 1, 2021. NPC proposes November 15, 2021 for this deadline.

(G) Preservation of Discoverable ESI Information

The parties have agreed to take the appropriate steps to preserve electronically stored information.

(H) Privilege Issues

NPC requests entry of a Rule 502(d) order, which will be submitted with the protective order. Plaintiff does not object to this request.

(I) Model Protocol for Discovery of ESI

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The parties intend to submit a proposed ESI Protocol or, in the alternative, briefing of any issues that cannot be agreed upon by August 28, 2020.

(J) Alternatives to Model Protocol

The parties have agreed to explore the possibility of coordinating discovery informally to coordinate with other ongoing Tasigna® cases.

IV. DISCOVERY COMPLETION DATE

Plaintiffs propose to complete discovery by August 3, 2021. NPC proposes September 3, 2021.

V. BIFURCATION

The parties do not seek bifurcation at this time.

VI. PRETRIAL STATEMENT AND PRETRIAL ORDER

The parties do not seek to dispense with pretrial statements and a pretrial order.

VII. INDIVIDUALIZED TRIAL PROGRAM

The Parties do not believe this Action is suitable for the Individualized Trial Program, pursuant to LCR 39.2.

VIII. OTHER PROPOSALS TO SHORTEN/SIMPLIFY THE CASE

NPC anticipates requesting that the Court conduct an evidentiary hearing related to the expected *Daubert* issues in this case and requests that the schedule allow time for an evidentiary hearing following the completion of *Daubert* briefing. NPC proposes that *Daubert* motions be due at the same time as summary judgment motions.

IX. TRIAL

Plaintiff anticipates trial readiness on December 1, 2021. The schedule proposed by Plaintiff provides thirteen (13) months to complete fact and expert discovery. Given the prior discovery conducted in the Lauris and McWilliams cases, and the progress that has already been made to date, it is Plaintiff's position that this schedule provides adequate time to achieve that goal. Plaintiff's proposed schedule also leaves three months between the close of

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discovery and trial readiness. Plaintiff believes this provides adequate time to address dispositive motions and complete relevant pre-trial work. Most importantly, it avoids the unnecessary delay created by NPC's proposal, which includes an unnecessary six (6) month gap between the close of discovery and trial.

NPC anticipates trial readiness on March 18, 2022. The schedule proposed by plaintiff does not provide adequate time to complete the necessary fact and expert discovery and the Court to decide dispositive and *Daubert* motions. Plaintiffs' proposed schedule provides only 90 days between the filing of dispositive motions and trial readiness, which does not build in sufficient time to complete pre-trial activities necessary to efficiently try this complex case, which the parties agree will take approximately 15 trial days. Those activities include NPC's anticipated request for evidentiary hearings on its *Daubert* motions, as well as the standard motions briefing schedule and time for the Court to decide the motions. There is also substantial pre-trial work which will be impacted by the resolution of those motions, including the scope and content of motions *in limine*, the parties' exhibit lists, and designations of deposition testimony.

NPC states that COVID-19 enhances the challenge of completing discovery and being ready for trial. For instance, the records collection process will likely require additional time because of the burden that the pandemic has put on healthcare providers and the possibility that offices, due to social distancing considerations, will not have extra staff available on-site to locate and copy needed records. Similarly, witness preparation schedules will be disrupted by various stay at home orders; while some of those orders are beginning to be lifted or relaxed, substantial restrictions on travel are expected to continue for months and that there will be 14-day quarantine requirements if individuals travel to certain areas. Given the unprecedented situation and the logistical hurdles surrounding COVID-19, NPC requests that the Court set a schedule that builds in additional time for the parties to work around these issues.

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It is Plaintiff's position that attempting to predict what, if any, impact COVID-19 will have on discovery efforts here is speculative at best and is not a valid basis for delaying trial at this time.

(A) JURY DEMAND

The parties request a jury trial at this time.

(B) ESTIMATED NUMBER OF TRIAL DAYS:

The parties estimate that this case will require approximately 15 trial days.

(C) KNOWN COMPLICATIONS WHICH WILL AFFECT TRIAL DATE:

The parties do not anticipate any complications to consider at this time.

(D) SERVICE ISSUES

N/A

(E) SCHEDULING CONFERENCE REQUESTED

Yes, the parties request a scheduling conference before the Court enters a scheduling order in the case.

(F) DATES CORPORATE DISCLOSURE STATEMENTS FILED

NPC filed its corporate disclosure statement on April 10, 2020.

Dated this 29th day of June, 2020.

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CERTIFICATE OF SERVICE

The undersigned declares under penalty of perjury, under the laws of the State of Washington, that the following is true and correct:

That on the 29th day of June, 2020, I arranged for service of the foregoing **JOINT STATUS REPORT AND DISCOVERY PLAN** to the parties to this action via the Court's CM/ECF system as follows:

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